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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/533,055

Applicant(s)

TAKEBE, MINORU

Examiner

Jennifer Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/27/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-4 are pending in the Application and under current examination.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Information Disclosure Statement filed on April 27, 2005 has been reviewed and considered, see the enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "strong" in claim 4 is a relative term which renders the claim indefinite. The term "strong" is not defined by the claim, the specification does not provide a

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standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, one of ordinary skill in the art would not be able to determine how much of superoxide scavenging activity is considered to be "strong" and how much of superoxide scavenging activity is consider to be "medium" or "weak". The specification disclose the preparation having superoxide scavenging activity of 12,000units/g in page 6, first full paragraph, table 1. Would a preparation having less than about 11,000units/g of superoxide scavenging activity still considered "strong" or "medium"? Would a preparation having more than 12,000units/g of superoxide scanvenging activity considered as being "super strong"? The term is relative as it varies from spectator to spectator.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 5,885,632).

Takebe et al. teach a food product comprising isoflavone aglycone, wherein the said isoflavone aglycone is comprised of 70-100wt.% daizein (tables 2 and 3, claims 7-10).

Applicant's recitation in claims 1-4 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the prior art.

Applicant's recitation in claim 2 of process of obtaining the product in claim 2 does not represent a patentable limitation in the "composition" claims because the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicant's recitation in claim 4 of the chemical property of having strong superoxide scavenging activity would be inherent property of the same composition

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taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising same active amounts (70-100wt%).

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 6,045,819).

Takebe et al. teach a product comprising isoflavone aglycone (claim 7), wherein the isoflavone aglycone is comprised of $\geq 70\%$ daizein (tables 5, 6 and 7).

Applicant's recitation in claims 1-4 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the prior art.

Applicant's recitation in claim 2 of process of obtaining the product in claim 2 does not represent a patentable limitation in the "composition" claims because the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicant's recitation in claim 4 of the chemical property of having strong superoxide scavenging activity would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising same active amounts (70-100wt%).

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Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Takebe et al. (U.S. Patent No. 6,303,161 B1).

Takebe et al. teach a product comprising isoflavone aglycone (table 4), wherein the isoflavone aglycone is comprised of $\geq 70\%$ daizein (tables 4, 5).

Applicant's recitation in claims 1-4 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the prior art.

Applicant's recitation in claim 2 of process of obtaining the product in claim 2 does not represent a patentable limitation in the "composition" claims because the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicant's recitation in claim 4 of the chemical property of having strong superoxide scavenging activity would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising same active amounts (70-100wt%).

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Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Obata et al. (U.S. Patent No. 6,444,239 B2).

Obata et al. teach a product comprising isoflavone aglycone (claim 1), wherein the isoflavone aglycone is comprised of 40% daizein (example 3).

Applicant's recitation in claims 1, 2 and 4 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the prior art.

Applicant's recitation in claim 2 of process of obtaining the product in claim 2 does not represent a patentable limitation in the "composition" claims because the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Applicant's recitation in claim 4 of the chemical property of having strong superoxide scavenging activity would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Kelly et al. (U.S. Patent No. 6,642,212).

Kelly et al. teach a composition comprising diadzein (isoflavone aglycone), wherein the diadzein is present in 95% of the composition (genistein:daizein =1:19), see claim 13).

Applicant's recitation in claims 1, 2 and 4 of an intended pharmaceutical use of treating sudden deafness does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the prior art.

Applicant's recitation in claim 2 of process of obtaining the product in claim 2 does not represent a patentable limitation in the "composition" claims because the determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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Applicant's recitation in claim 4 of the chemical property of having strong superoxide scavenging activity would be inherent property of the same composition taught by cited prior art comprising same active agent of isoflavone aglycone (daidzein) comprising 95% active amounts (at least 70wt%).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1- 4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of U.S. Patent No. 5,885,632.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application

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and the cited patent are each drawn to a material comprising the product comprising isoflavone aglycone. The claims of the present application and the cited patent differ in that the claims of the cited patent do not recited the amounts of daizein of at least 70%wt, however, the subject matter has been taught in the specification (e.g. tables 2 and 3). Therefore, it would have been obvious to one of ordinary skill in the art to formulate the isoflavone aglycone composition comprising daizein with the specific amounts illustrated and taught in the patent.

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,045,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application and the cited patent are each drawn to a product comprising isoflavone aglycone. The claims of the present application and the cited patent differ in that the claims of the cited patent do not recited specific isoflavone aglycone (daizein) and the amounts of daizein of at least 70%wt, however, the subject matter has been taught in the specification (e.g. tables 5, 6 and 7). Therefore, it would have been obvious to one of ordinary skill in the art to formulate the isoflavone aglycone composition comprising daizein with the specific amounts illustrated and taught in the patent.

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-9 of U.S. Patent No. 6,303,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because claims of the cited patent encompasses the instant claims. The claims of the present application and the cited patent are each drawn to a product comprising isoflavone aglycone. The claims of the present application and the cited patent differ in that the claims of the cited patent do not recite the product comprising isoflavone aglycone and the amounts of daizein of at least 70%wt, however, the subject matter has been taught in the specification (e.g. tables 4, 5). Therefore, it would have been obvious that the product taught in the patent encompasses instant claims since the resulted component and the product is illustrated and taught in the specification on table 4, 5 comprising same isoflavone aglycone (daizein) with instantly claimed amounts.

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 9-13 and 15 of copending Application No. 10/070888. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of cited co-pending Application encompasses the instant claims. The claims of the present application and the cited co-pending Application are each drawn to a product comprising isoflavone

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aglycone, daizein comprising at least 70% of daizein. Although the intended use differ because of the claims in the co-pending Application state that the product is intended for a somatic stem cell-augmenting material, however, the intended use does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the co-pending Application as it teaches same active agent of daizein with same amounts drawn to a product claim. Therefore, the invention as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/070889. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of cited co-pending Application encompasses the instant claims. The claims of the present application and the cited co-pending Application are each drawn to a product comprising isoflavone aglycone, daizein comprising at least 70% of daizein. Although the intended use differ because of the claims in the co-pending Application state that the product is intended for an anti-obesity material, however, the intended use does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the co-pending Application encompassing same active agent of daizein with same amounts drawn to a product claim. Therefore, the invention as claimed are co-extensive.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 10/507,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of cited co-pending Application encompasses the instant claims. The claims of the present application and the cited co-pending Application are each drawn to a product comprising isoflavone aglycone, daizein comprising at least 70% of daizein. Although the intended use differ because of the claims in the co-pending Application state that the product is intended for promoting biological activity which is broader since the promotion of biological activity encompasses prevention and treatment of a disease, however, the intended use does not represent a patentable limitation since such fails to impart any physical limitation to the same composition in the co-pending Application encompassing same active agent of daizein with same amounts drawn to a product claim. Therefore, the invention as claimed are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

None of the claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
October 30, 2006